

Prescription Drugs With Foreign Labels

Prepared for Rep. Henry A. Waxman

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U.S. House of Representatives**

The drug importation provisions in the Agriculture Appropriations bill contain several significant loopholes. One major loophole is created by the fact that foreign drug labels generally differ from the FDA-approved labels that must be used in the United States. In effect, the bill creates a labeling "Catch-22" for would-be U.S. importers.

As the bill is currently drafted, U.S. importers cannot import foreign drugs with labels that differ from the FDA-approved label. But U.S. importers cannot relabel the drugs with FDA-approved labels because doing so would violate the copyright and trademark protections held by the drug manufacturers. An amendment offered by Rep. Delauro to give U.S. importers the right to use the FDA-approved labels was voted down on a party line vote (9-6) during the conference.

The following discussion provides more information about this labeling "Catch 22," along with examples of foreign drugs with labels that differ from the FDA-approved labels.

Selling drugs without the FDA-approved label is misbranding. Prescription drug labels provide basic information on the drug, its formulation, the manufacturer and distributor, and how it is used. Every country has different labeling requirements. In the United States, when a company files an application for approval of a new drug, the company submits the label to FDA. Any deviation from the label submitted by the manufacturer without prior FDA approval constitutes misbranding of the drug. The penalties for misbranding under the Federal Food, Drug, and Cosmetic Act include fines and imprisonment.

Some drugs are sold under different names in the different countries. Prilosec, an ulcer medication made by Merck, was the number one selling drug in the United States in 1999. It is much more expensive in the United States (\$120.45 for thirty 20 mg pills) than in Canada (\$51.60) or Mexico (\$34.50). However, in Canada and Mexico, the drug is sold under a different brand name: Losec. Because of this difference in names, the Canadian or Mexican labels are not the FDA-approved label. Bringing Prilosec into the United States with the Canadian or Mexican label is misbranding.

Attachment 1 displays the United States and Canadian labels for Prilosec/Losec.

Drug labels can be in different languages. In the United States, approved drug labels are in English (sometimes FDA also approves labels with some information in Spanish). In Mexico, labels are in Spanish; in Italy, labels are in Italian. Canadian drug labels are bilingual, in French

and English. Labels that are not in English, or that are bilingual English-French labels, differ from the FDA-approved label. Distributing drugs with these labels is misbranding.

Attachment 2 displays the United States and Canadian labels for Prozac, an antidepressant manufactured by Eli Lilly. The Canadian version of the label is a bilingual English-French label.

Drug labels can have different identification numbers. In the United States, all approved drugs receive an FDA identification number, known as a National Drug Code number. This number appears on virtually all U.S. labels. In Canada, however, approved drugs have a different number, a Drug Information Number (DIN). The DIN appears on all Canadian labels. Because the U.S. NDC code and the Canadian DIN are different, Canadian labels differ from the FDA-approved label, and selling a drug with a Canadian DIN in the United States constitutes misbranding.

Attachment 3 displays the United States and Canadian labels for Cipro, a popular antibiotic manufactured by Bayer. The different identification numbers are visible on the upper right corners of the labels.

Drugs are often distributed by different entities in different countries. When a manufacturer submits an application for approval of a new drug, the manufacturer must identify all the distributors of the drug. In many cases, the distributors of the drugs in the United States are different from the distributors in other countries. For example, the popular diabetes drug Glucophage is distributed in the United States by Bristol-Myers Squibb. However, when sold in Canada, the drug is distributed by Nordic Laboratories. If the Canadian distributor is not approved by FDA, drugs with labels listing this distributor differ from the FDA-approved label and cannot be sold in the United States.

Attachment 4 displays the United States and Canadian labels for Glucophage.

Drugs can have different indications. For some drugs, the indication information provided on labels from other countries is not the same as the U.S. information. For example, Dilantin, an anticonvulsant manufactured by Parke-Davis, contains the following information on the Canadian label:

Adults, initially 1 capsule 3 times daily with subsequent doses individualized to a maximum of six doses daily. Usual maintenance dose is 3 to 4 capsules daily.
Children over 6 years of age, 1 capsule three times daily or as directed by physician.

The U.S. label contains slightly different information for adults and no dosage information for children. The U.S. label states: "Adults, 1 capsule three or four times daily or as directed." Because the United States and Canadian versions of the drug label contain different dosage information, the drug cannot be sold in the United States with the Canadian label.

Attachment 5 displays the United States and Canadian labels for Dilantin.

United States Label

NDC 0186-0741-68

Prilosec®
(omeprazole)

40 mg

0186-0743-68

100 Delayed-Release Capsules

Manufactured by:
MERCK & CO., Inc.
West Point, PA 19386

Distributed by:
ASTRA®
Astra Pharmaceuticals, L.P., Wayne, PA 19080

Lot

K5363 EXP SEP01

Canadian Label

Keep capsules light tight. Protect from heat and moisture. Store between 15°C and 25°C (59°F and 77°F). The LOSEC (Omeprazole, MSD) Delayed-Release Capsules should be swallowed whole; not chewed, crushed, or melted.

30 DELAYED-RELEASE CAPSULES

LOSEC® 20 mg
(OMEPRAZOLE, MSD)

Jointly manufactured by:
MERCK SHARP & DOHME
DIV OF MERCK & CO., INC., WEST POINT, PA 19386, USA

and
AB ASTRA
SÖDERÅLLEN, SWEDEN

Lot

Exp.

NDC 0006-0727-31

30 DELAYED-RELEASE CAPSULES

LOSEC® 20 mg
(OMEPRAZOLE, MSD)

Jointly manufactured by:
MERCK SHARP & DOHME
DIV OF MERCK & CO., INC., WEST POINT, PA 19386, USA

and
AB ASTRA
SÖDERÅLLEN, SWEDEN

Lot

Exp.

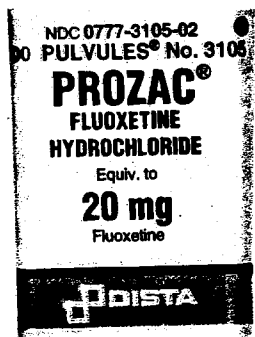
CAUTION: Federal (USA) law prohibits dispensing without prescription.
A PRODUCT OF ASTRAMERCK RESEARCH
USUAL ADULT DOSE: See accompanying circular.
BIOGEN is a registered trademark of
MERCK & CO., Inc.
LOSEC is a registered trademark of
AB ASTRA

763402

30 | No. 3427 LIFT HERE

Attachment 1

United States Label



Canadian Label

P 3105 100 DIN 636622

PROZAC®
FLUOXETINE HYDROCHLORIDE CAPSULES
CAPSULES DE CHLORHYDRATE DE FLUOXÉTINE
20 mg
Fluoxétine 20 mg/capsule
Fluoxétine 20 mg/capsule
ANTIDÉPRESSANT/ANTIDÉPRESSEUR
Eli Lilly Canada Inc., Toronto, Ontario
© Un produit de la division Lilly Canada de Eli Lilly and Company
Le médicament est une marque de Eli Lilly and Company

Adult dosage—Initial dosage 20 mg once daily in the morning. A gradual dose increase may be considered after several weeks if no improvement is observed. Maintain at lowest effective dose. Dosage should not exceed 80 mg/day.

Not recommended for use in patients under 18 years of age.

Product Monograph available on request.

Posologie pour adultes—La posologie initiale est de 20 mg une fois par jour le matin. La dose peut être augmentée progressivement après plusieurs semaines si l'on n'observe pas d'amélioration. Maintenir la posologie à la dose minimale efficace. La posologie ne doit pas dépasser 80 mg par jour.

Non recommandé chez les patients de moins de 18 ans.

Monographie sur demande.

KEEP TIGHTLY CLOSED
GARDER HERMÉTIQUEMENT
FERRÉ
PROTECT FROM LIGHT
CRANT LA LUMIÈRE
YK 9900 CCAX
Etc.

United States Label

851310

NDC 0026-8513-51



CIPRO®

(ciprofloxacin hydrochloride)

Equivalent to

500 mg ciprofloxacin

100 Tablets

R. Only



Bayer

Bayer Corporation
Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516

Canadian Label

851213

DIN 02155958



CIPRO® 250

ciprofloxacin hydrochloride tablets
comprimés de
chlorhydrate de ciprofloxacine
USP

250 mg ciprofloxacin/tablet
comprimés à 250 mg de ciprofloxacine

Antibacterial agent/Antibactérien



100 Tablets
comprimés

United States Label

100 Tablets NDC 0087-6060-05

GLUCOPHAGE®
(metformin hydrochloride
tablets)

Rx only

500
mg

Bristol-Myers Squibb Company

Canadian Label

No. 2509

500 comprimés
tablets

GLUCOPHAGE®

Comprimés de
**CHLORHYDRATE DE
METFORMINE / METFORMIN
HYDROCHLORIDE**
Tablets

Norme Nordic Standard
500 mg

Antihyperglycémiant
Antihyperglycemic

DIN 00314552

NORDIC
LABORATOIRES NORDIC INC
NORDIC LABORATORIES INC
Laval, Q.C. (Canada) H7L 3M7

Chaque comprimé contient:
Chlorhydrate de
Metformine500 mg

POSOLOGIE

ADULTES: 1 comprimé
(0.5 g) 3 à 4 fois par jour du-
rant les repas. La dose maxi-
male quotidienne de 2.5 g ne
devrait pas être dépassée.
L'augmentation de la dose
doit être graduelle afin de
minimiser les troubles gas-
tro-intestinaux.

Monographie disponible sur
demande.



FABRIQUÉ SOUS LICENCE DE
LIPHA SA, LYON, FRANCE

7 70258 25094 5

Each tablet contains:

Metformin
Hydrochloride500 mg

DOSAGE

ADULTS: 1 tablet (0.5 g), 3 to
4 times daily during meals. A
maximum daily dose of 2.5 g
should not be exceeded.
Dosage should be increased
gradually to minimize gas-
trointestinal disorders.

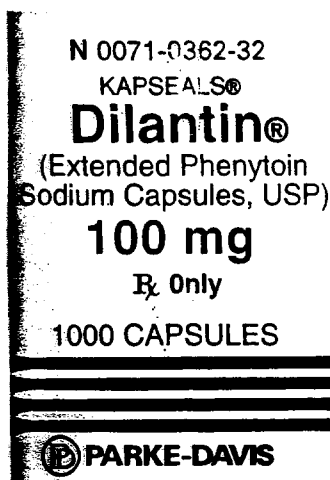
Product monograph avail-
able upon request.



MADE UNDER LICENCE
FROM LIPHA SA, LYON, FRANCE

E-2509-500-D

United States Label



NOTE TO PHARMACIST—
Do not dispense capsules which
are discolored.

**Dosage—Adults, 1 capsule three or
four times daily or as directed.**

See package insert under cap for
complete prescribing information.

Keep this and all drugs out of the
reach of children.

Dispense in a tight, light-resistant
container as defined in the USP.

Store below 30°C (86°F). Protect
from light and moisture.

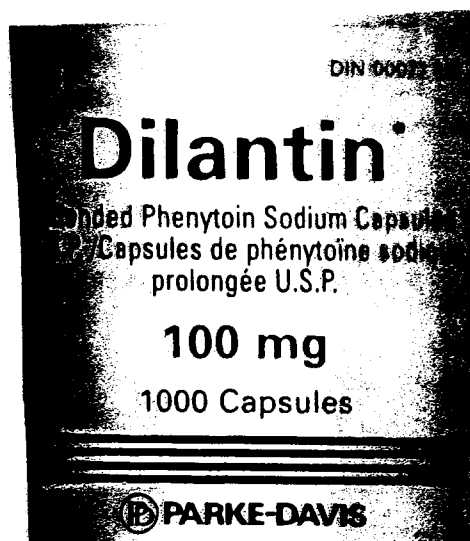
Exp date and lot

03/02

01040F

0342G420

Canadian Label



Anticonvulsant/Anticonvulsant

**Dosage: Adults, initially 1 capsule 3 times
daily with subsequent doses individ-
ualized to a maximum of 6 capsules daily.
Usual maintenance dose is 3 to 4 capsules
daily. Children over 6 years of age, 1
capsule 3 times daily or as directed by
physician.**

Product Monograph available to
physicians and pharmacists on request.

Store at room temperature below 30°C
(86°F). Protect from light and moisture.

**Posologie : Adultes : commencer par
1 capsule, 3 fois par jour, puis adapter la
posologie selon les besoins de chaque
patient; maximum de 6 capsules par jour.
La dose d'entretien habituelle est de
3 à 4 capsules par jour. Enfants âgés de
plus de 6 ans : 1 capsule, 3 fois par jour ou
selon les indications du médecin.**

Monographie fournie aux médecins et aux
pharmaciens sur demande.

Conserver à une température ambiante à
moins de 30°C (86°F). Craint la lumière et
l'humidité.